IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

OTSUKA PHARMACEUTICAL CO., LTD. AND H. LUNDBECK A/S, Plaintiffs, v. AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS, INC., AMNEAL PHARMACEUTICALS COMPANY GMBH, RAKS PHARMA PVT. LTD., AMNEAL PHARMACEUTICALS OF NEW YORK, LLC AND AMNEAL EU, LTD., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Otsuka Pharmaceutical Co., Ltd. ("Otsuka") and H. Lundbeck A/S ("Lundbeck") (collectively, "Plaintiffs"), by way of Complaint against Defendants Amneal Pharmaceuticals, Inc. ("Amneal Inc."), Amneal Pharmaceuticals LLC ("Amneal LLC"), Amneal Pharmaceuticals Company GmbH ("Amneal GmbH"), Raks Pharma Pvt. Ltd. ("Raks") (collectively, "Amneal I"), Amneal Pharmaceuticals of New York, LLC ("Amneal New York") and Amneal EU, Ltd. ("Amneal EU"), (collectively with Amneal I referred to herein as "Amneal"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of Reissue Patent No. RE48,059 ("the RE'059 patent"), arising under the United States patent laws, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Amneal's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug

and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to engage in the commercial manufacture, use and/or sale of generic pharmaceutical products before the expiration of the RE'059 patent.

THE PARTIES

2. Otsuka is a corporation organized and existing under the laws of Japan with its corporate headquarters at 2-9 Kanda Tsukasa-machi, Chiyoda-ku, Tokyo, 101-8535, Japan.

3. Lundbeck is a corporation organized and existing under the laws of Denmark, with a place of business at Ottiliavej 9, DK-2500 Valby, Denmark. Otsuka has granted Lundbeck an exclusive license to the RE'059 patent.

4. Otsuka and Lundbeck are engaged in the business of researching, developing and bringing to market innovative pharmaceutical products.

5. Upon information and belief, Amneal Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

6. Upon information and belief, Amneal LLC is a limited liability company organized under the laws of Delaware and its principal place of business is located at 400 Crossing Boulevard, Bridgewater, New Jersey 08807. Upon information and belief, Amneal LLC is a wholly owned subisidiary of Amneal Inc.

7. Upon information and belief, Amneal GmbH is a limited liability company organized under the laws of Switzerland and its principal place of business is located at Turmstrasse 30 5312, Steinhausen, Switzerland. Upon information and belief, Amneal GmbH is a wholly owned subsidiary of Amneal Inc. and Amneal LLC.

8. Upon information and belief, Raks is a corporation organized under the laws of India and its principal place of business is located at Plot No. 68, Survey No. 60, 62 & 63, Jawaharlal Nehru Pharma City, E-Bonangi Revenue Village, Parawada Mandal, Visakhapatnam 531 021, Andhra Pradesh, India. Upon information and belief, Raks is a wholly owned subsidiary of Amneal Inc. and Amneal LLC.

9. Upon information and belief, Amneal New York is a limited liability corporation organized under the laws of Delaware, having a principal place of business at 50 Horseblock Road, Brookhaven, New York 11719. Upon information and belief, Amneal New York is a wholly owned subsidiary of Amneal Inc. and Amneal LLC.

10. Upon information and belief, Amneal EU is a company organized under the laws of Ireland and its principal place of business is located at 70 Sir John Rogerson's Quay, D02 R296 Dublin, Ireland. Upon information and belief, Amneal EU is a wholly owned subsidiary of Amneal GmbH, Amneal Inc. and Amneal LLC.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Amneal Inc. Upon information and belief, Amneal Inc. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal Inc. directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

13. Upon information and belief, Amneal Inc. admits it has a "generics portfolio of

more than 250 medicines" in the United States. https://www.amneal.com/products/our-portfolio (accessed Sept. 24, 2020). Upon information and belief, Amneal Inc. admits its "generics business has grown to be among the largest in the U.S." https://www.amneal.com/products/our-portfolio/generic-products (accessed Sept. 24, 2020).

14. This Court has personal jurisdiction over Amneal LLC. Upon information and belief, Amneal LLC is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal LLC directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal LLC purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

15. Upon information and belief, Amneal LLC "is a generic pharmaceutical company specializing in developing, manufacturing, marketing and distributing high-value generic pharmaceutical products across a broad array of dosage forms and therapeutic areas." Amneal Pharmaceuticals, Inc., Final Prospectus Filed Pursuant to Rule 424(b)(3) 10 (May 9, 2018).

16. Upon information and belief, Amneal LLC "manufactures, markets and/or distributes more than 225 drugs in the United States." https://www.drugs.com/manufacturer/amneal-pharmaceuticals-llc-19.html (accessed Sept. 24, 2020).

17. Upon information and belief, Amneal LLC has active pharmacy wholesale licenses in the state of Delaware with license numbers A4-0002541, A4-0002542 and A4-0002655, and active controlled substances distributor/manufacturer licenses in the state of Delaware with the license numbers DM-0013197 and DM-0013893.

18. This Court has personal jurisdiction over Amneal GmbH. Upon information and belief, Amneal GmbH is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal GmbH directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal GmbH purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

19. Upon information and belief, Amneal GmbH is the international headquarters for Amneal. https://www.amneal.com/contact (accessed Sept. 24, 2020).

20. Upon information and belief, Amneal GmbH is engaged in the development and/or manufacturing of Amneal's generic products. Upon information and belief, Amneal GmbH applied for one or more patent applications directed to the preparation of brexpiprazole. *See*, *e.g.*, International Publication No. WO 2018/172463, titled "Process for the Preparation of Brexpiprazole," designating the United States for the national phase.

21. This Court has personal jurisdiction over Raks. Upon information and belief, Raks is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Raks directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Raks purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

22. Upon information and belief, Raks is the holder of FDA Drug Master File No. 33451 for brexpiprazole.

23. Upon information and belief, this Court has personal jurisdiction over Amneal New York. Upon information and belief, Amneal New York is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal New York directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal New York purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

24. Upon information and belief, Amneal New York is the U.S. agent for Amneal's ANDA No. 213562.

25. Upon information and belief, this Court has personal jurisdiction over Amneal EU. Upon information and belief, Amneal EU is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Amneal EU directly, or indirectly, develops, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Amneal EU purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Amneal's generic products.

26. Upon information and belief, Amneal EU admits it "is in the business of providing pharmaceutical products for sale in the United States." *Cubist Pharms. LLC v. Amneal Pharms. LLC, et al.*, C.A. No. 3:19-cv-15439 (D.N.J. June 4, 2020), D.I. 48 at ¶ 6. Upon information and belief, Amneal EU is the ANDA holder for ANDA 213562.

27. Upon information and belief, Amneal Inc., Amneal LLC, Amneal GmbH, Raks, Amneal New York and Amneal EU hold themselves out as a unitary entity and operate as a single

integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

28. Amneal's ANDA filing regarding the RE'059 patent relates to this litigation and is substantially connected with this judicial district because it reliably and non-speculatively predicts Amneal's intent to market and sell Amneal's generic products in this judicial district.

29. Amneal has taken the significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—which, upon information and belief, will be purposefully directed at the District of Delaware and elsewhere throughout the United States. Upon information and belief, Amneal intends to direct sales of its generic drugs in this judicial district, among other places, once Amneal receives the requested FDA approval to market its generic products. Upon information and belief, Amneal will engage in marketing of its proposed generic products in Delaware upon approval of its ANDA.

30. Upon information and belief, Amneal has thus been, and continues to be, the prime actor in the drafting, submission, approval and maintenance of its ANDA No. 213562.

31. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Amneal Inc., Amneal LLC and Amneal New York are incorporated in the state of Delaware.

32. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Amneal GmbH is incorporated in Switzerland, Raks is incorporated in India and Amneal EU is incorporated in Ireland, all of whom may be sued in any judicial district.

FACTUAL BACKGROUND

The NDA

33. Otsuka is the holder of New Drug Application ("NDA") No. 205422 for REXULTI® (brexpiprazole) Tablets in 0.25, 0.5, 1, 2, 3, and 4 mg dosage forms ("REXULTI® Tablets").

34. The FDA approved NDA No. 205422 on July 10, 2015.

35. REXULTI® Tablets are prescription drugs approved for the adjunctive treatment of major depressive disorder and the treatment of schizophrenia. Brexpiprazole is the active ingredient in REXULTI® Tablets.

The Patent In Suit

36. The United States Patent and Trademark Office ("the PTO") issued U.S. Patent No. 7,888,362 ("the '362 patent") on February 15, 2011, entitled "Piperazine-Substituted Benzothiophenes for Treatment of Mental Disorders."

37. The PTO reissued the '362 patent as the RE'059 patent on June 23, 2020. A true and correct copy of the RE'059 patent is attached hereto as Exhibit A.

38. As the reissue of the '362 patent, Otsuka owns the RE'059 patent through assignment as recorded by the PTO for the '362 patent at Reel 048501, Frame 0122; Reel 021939, Frame 0746 and Reel 048501, Frame 0166.

39. Pursuant to 35 U.S.C. § 251, the RE'059 patent issued for the unexpired term of the '362 patent, which would have expired on April 12, 2026, by virtue of a terminal disclaimer filed in the PTO that disclaimed 317 days of patent term adjustment granted to the '362 patent under 35 U.S.C. § 154(b). A true and correct copy of the terminal disclaimer is attached as Exhibit B.

40. Otsuka filed a Submission Pursuant to 37 C.F.R. § 1.765 for Patent Term Extension Application Under 35 U.S.C. § 156 and Response to Notice of Final Determination, requesting an extension under 35 U.S.C. § 156(c) of 986 days for the '362 patent. After the RE'059 patent issued, Otsuka filed a Petition Under 37 C.F.R. § 1.182 to Move Patent Term Extension Application from U.S. Patent No. 7,888,362 to RE 48,059. Accordingly, the RE'059 patent will expire on December 23, 2028, based on the 986 days of Patent Term Extension under 35 U.S.C. § 156(c).

41. The RE'059 patent is listed in Approved Drug Products With Therapeutic Equivalence Evaluations ("the Orange Book") in connection with NDA No. 205422 for REXULTI® (brexpiprazole) Tablets.

The ANDA

42. Upon information and belief, Amneal filed ANDA No. 213562 with the FDA under 21 U.S.C. § 355(j) seeking FDA approval to engage in the commercial manufacture, use and/or sale in the United States of brexpiprazole tablets, 0.25, 0.5, 1, 2, 3 and 4 mg ("Amneal's generic products"), which are generic versions of Otsuka's REXULTI® (brexpiprazole) Tablets.

43. Otsuka received a letter sent by Amneal I, dated September 9, 2019, purporting to be a "Notice of Paragraph IV Certification" for its ANDA ("Amneal I's September 9, 2019, Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I), (iv)(I) and 21 C.F.R. § 314.95(c). Amneal I's September 9, 2019, Notice Letter notified Otsuka that Amneal I had filed an ANDA seeking approval to engage in the commercial manufacture, use and/or sale of Amneal's generic products before the expiration of the '362 patent and U.S. Patent Nos. 8,349,840 ("the '840 patent"), 8,618,109 ("the '109 patent"), 9,839,637 ("the '637 patent") and 10,307,419 ("the '419 patent").

44. In response to Amneal I's September 9, 2019, Notice Letter, Plaintiffs previously filed a separate action in this Court against Amneal I for patent infringement, which included counts of infringement of the '362, '840, '109, '637 and '419 patents. *See Otsuka Pharmaceutical Co., Ltd., et al. v. Amneal Pharmaceuticals LLC, et al.*, C.A. No. 19-1952-LPS.

45. On June 23, 2020, the PTO issued the RE'059 patent as a reissue of the '362 patent. Plaintiffs timely notified the FDA and the RE'059 patent was listed in the Orange Book for REXULTI®.

46. Upon information and belief, ANDA No. 213562 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the RE'059 patent are invalid, unenforceable and/or would not be infringed by Amneal's generic products.

47. Otsuka received a letter sent by Amneal, dated August 13, 2020, purporting to be a "Notice of Paragraph IV Certification" for ANDA No. 213562 ("Amneal's August 13, 2020, Notice Letter") pursuant to 21 U.S.C. § 355 (j)(2)(B)(ii)(I). Amneal's August 13, 2020, Notice Letter notified Otsuka that Amneal had filed ANDA No. 213562, seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation in the United States of Amneal's generic products before the expiration of the RE'059 patent.

48. Plaintiffs commenced this action within 45 days of receiving Amneal's August 13, 2020, Notice Letter.

COUNT I

(INFRINGEMENT OF THE RE'059 PATENT)

49. Plaintiffs reallege, and incorporate fully herein, each preceding paragraph.

50. Upon information and belief, Amneal filed ANDA No. 213562 seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the RE'059 patent.

51. Upon information and belief, Amneal filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the RE'059 patent are invalid, unenforceable and/or not infringed.

52. Upon information and belief, in its ANDA No. 213562, Amneal has represented to the FDA that Amneal's generic products are pharmaceutically and therapeutically equivalent to Otsuka's REXULTI® Tablets.

53. Amneal has actual knowledge of Otsuka's RE'059 patent, as evidenced by Amneal's August 13, 2020, Notice Letter.

54. Upon information and belief, under 35 U.S.C. § 271(e)(2)(A), Amneal has infringed one or more claims of the RE'059 patent by submitting, or causing to be submitted, to the FDA ANDA No. 213562, seeking approval to commercially manufacture, use, import, offer to sell or sell Amneal's generic products before the expiration date of the RE'059 patent.

55. Upon information and belief, if ANDA No. 213562 is approved, Amneal intends to and will offer to sell, sell and/or import in the United States Amneal's generic products.

56. Upon information and belief, if ANDA No. 213562 is approved, Amneal will infringe one or more claims of the RE'059 patent under § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and/or importing Amneal's generic products, and/or by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any

FDA approval of ANDA No. 213562 shall be no earlier than the expiration of the RE'059 patent and any additional periods of exclusivity.

57. Upon information and belief, Amneal's actions relating to Amneal's ANDA No. 213562 complained of herein were done by and for the benefit of Amneal.

58. Plaintiffs will be irreparably harmed by Amneal's infringing activities unless this Court enjoins those activities.

59. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Amneal has infringed at least one claim of each of the patents in suit through Amneal's submission of ANDA No. 213562 to the FDA seeking approval to manufacture, use, import, offer to sell and/or sell Amneal's generic products in the United States before the expiration of the RE'059 patent;

B. The entry of judgment under 35 U.S.C. § 271(a), (b) and/or (c) that Amneal's making, using, offering to sell, selling or importing of Amneal's generic products before the expiration of the RE'059 patent will infringe, actively induce infringement and/or contribute to the infringement of the RE'059 patent under 35 U.S.C. § 271(a), (b) and/or (c);

C. The issuance of an order that the effective date of any FDA approval of Amneal's generic products shall be no earlier than the expiration date of the patents in suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. The entry of a preliminary and/or permanent injunction, enjoining Amneal and all persons acting in concert with Amneal from commercially manufacturing, using, offering for sale or selling Amneal's generic products within the United States, or importing Amneal's generic

products into the United States, until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. The entry of a preliminary and/or permanent injunction, enjoining Amneal and all persons acting in concert with Amneal from seeking, obtaining or maintaining approval of ANDA No. 213562 until the expiration of the RE'059 patent, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of their costs, expenses and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

ASHBY & GEDDES

/s/ Steven J. Balick

Steven J. Balick (#2114)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, Delaware 19899
(302) 654-1888
sbalick@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Plaintiffs Otsuka Pharmaceutical Co., Ltd. and H. Lundbeck A/S

Of Counsel:

James B. Monroe
Denise Main
Erin M. Sommers
C. Collette Corser
Tyler B. Latcham
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4431
(202) 408-4000

Dated: September 25, 2020